

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of
CATT et al.

Group Art Unit: 1743

Appln. No.: 08/801,212

Examiner: J. SNAY

Filed: February 18, 1997

FOR: MONITORING METHODS

August 2, 2000

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231



Sir:

Attached is Form PTO-1449 listing the documents related to this application. Since there are a large number of documents listed (12 pages) and all of the documents listed are related in a number of applications filed by the above applicant, Examiner Pamela Wingood of Group 3736 has agreed to hold the original copy of the listed documents. The documents were originally filed in application no. 08/772,522, on June 27, 2000.

This IDS is intended to be in full compliance with the rules, but should the Examiner find any part of its required content to have been omitted, prompt notice to that effect is earnestly solicited, along with additional time under Rule 97(f), to enable Applicant to comply fully.

If it is determined that any fee is required to file this IDS, the Patent Office is authorized to charge that fee from our deposit account 033975 with the notation for this matter number 236546.

Applicants respectfully request the Examiner to consider each of the documents supplied herewith. It is furthermore respectfully requested that the Examiner confirm the careful and

CATT et al - Application No. 08/801,212

independent consideration in the next official communication by return of an initialed and dated
PTO-1449 form in accordance with the provisions of MPEP 609.

Respectfully submitted,

PILLSBURY MADISON & SUTRO LLP

By _____

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236546

R3247 C

INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

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U.S. PATENT DOCUMENTS:

Examiner's Initials*	Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
	AR 3,141,740	07/1964	Wild			
	BR 3,406,016	10/1968	FOSTER et al.			
	CR 3,406,015	10/1968	Foster			
	DR 3,434,801	03/1969	Scherr			
	ER 3,436,186	04/1969	Mcsweeney et al.			
	FR 3,749,089	07/1973	Derr			
	GR 3,875,013	04/1975	MANAUTOU et al.			
	HR 3,924,609	12/1975	FRIEDENBERG et al.			
	IR 3,926,037	12/1975	Kopito et al.			
	JR 3,968,011	07/1976	Manautou et al.			
	KR 3,986,494	10/1976	Preti et al.			
	LR 3,991,174	11/1976	Grundman			
	MR 4,002,056	01/1977	Kopito et al.			
	NR 4,010,738	03/1977	Preti et al.			

FOREIGN PATENT DOCUMENTS:

	Document Number	Date MM/YYYY	Country	Inventor Name	English Abstract		Translation Readily Available	
					Enclosed	No	Enclose	No
	OR 0 011 594	12/1984	EPO	DESJACQUES				X
	PR 0 097 851	06/1983	EPO	MENKE et al.			X	
	QR 0 132 199	07/1984	EPO	TRAFFORD et al.			X	
	RR 0 177 994	01/1990	EPO	REGAS et al.				X
	SR 0 195 207	01/1986	EPO	FROHN et al.				X
	TR 0 225 054	10/1986	EPO	PERRY et al.			X	
	UR 0 286 743	04/1987	EPO	KOSASKY			X	
	VR 0 291 194	04/1988	EPO	MAY et al.			X	
	WR 0 339 092	12/1987	EPO	MATSUURA			X	
	XR 0 367 615	11/1989	EPO	GLAZE			X	

OTHER (including in this order: Author, Title, Periodical Name, Date, Pertinent Pages, etc.):

YR	Adlercreutz et al., "Prediction of ovulation by urinary estrogen assays", J. Steroid Biochem, 1980, v. 12, pp 395-348			
ZR	Adlercreutz et al., "The measurement of urinary steroid glucuronides as indices of the fertile period in women", J. Steroid Biochem, 1982, v. 17, pp 695-702			
AAR	Albertson et al., "Review Article: The prediction of ovulation and monitoring of the fertile period", Adv. Contracept, v. 3, pp 263-290			
BBR	Baird et al., "Using the ratio of urinary oestrogena nd progesterone metabolites to estimate day of ovulation", Statistics in Medicine, 1991, 10, pp 255-266			
CCR	Barnard et al., "A nonseparation, time-resolved fluoroimmunoassay to minitor ovarian function and predict potential fertility in women", Fertility and Sterility, 1989, 52(1), pp 60-65			
DDR	Bieglmayer et al., "Evaluation of a simple and fast self-test for urine luteinizing hormone", Fertility and Sterility, 1990, 53(5), pp 842-846			

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	AR 4,013,066	03/1977	Schuster			
	BR 4,031,365	06/1977	Raggiotti et al.			
	CR 4,036,212	07/1977	Karuhn			
	DR 4,059,986	11/1977	Schuster			
	ER 4,072,045	02/1978	Kopito			
	FR 4,119,089	10/1978	Preti et al.			
	GR 4,123,510	10/1978	Banik et al.			
	HR 4,148,304	04/1979	Mull			
	IR 4,151,831	05/1979	Lester			
	JR 4,151,833	05/1979	Polishuk			
	KR 4,208,187	06/1980	Givner			
	LR 4,232,215	11/1980	Hanley			
	MR 4,246,907	01/1981	Bullock			
	NR 4,261,371	04/1981	Reading, III			

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					Enclosed	No	Enclose	No
	OR 0 383 619	02/1990	EPO	DAVIS et al.			X	
	PR 0 385 621	02/1990	EPO	COLEY et al.			X	
	QR 0 424 102	10/1990	EPO	NISHIMURA			X	
	RR 0 470 507	08/1991	EPO	LO SAPIO et al.			X	
	SR 0 476 703	09/1991	EPO	NISHIMURA et al.			X	
	TR 0 498 303	01/1992	EPO	WEINMANN			X	
	UR 0 653 625	11/1994	EPO	CATT et al.			X	
	VR WO 80/02800	12/1980	WIPO	OSTER et al.			X	
	WR WO 84/03381	08/1984	WIPO	AESCHLIMANN	X			X
	XR WO 87/02774	05/1987	WIPO	BAKER et al.			X	

OTHER (Including in this order: Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

YR	Bischof et al., "Comparison of a rapid, quantitative and automated assay for urinary luteinizing hormone (LH), with an LH detection test, for the prediction of ovulation", Human Reproduction, 1991, 6(4), pp 515-518			
ZR	Bonnar, "Biological methods of identifying the fertile period", Fertility and Sterility, 1984, Eds. Harrison et al., MTP Press, pp 77-92			
AAR	Brown et al., "Appendix 1: Correlations between the mucus symptoms and the hormone markers of fertility throughout reproductive life", The Ovulation Method, 7 th Ed., Ed. Bilings, Advocate Press, Melbourne, 1983, pp 99-125			
BBR	Brown et al., "Natural Family Planning", Am. J. Obstet. Gynecol, 1987, 157(4), Part 2, pp 1082-1089			
CCR	Brown et al., "Chemical and homogeneous immunoassay methods for the measurement of estrogens and pregnanediol and their glucuronides in urine", Non-Radiometric Assays: Technology and Application in Polypeptide and Steroid Hormone Detection, Publ. Alan R. Liss Inc., 1988, pp 119-138			
DDR	Brown et al., "New assays for identifying the fertile period", Int. J. Gynecol Obstet, Suppl. 1, 1989, pp 111-122			

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	AR 4,312,360	01/1982	Conway et al.			
	BR 4,367,527	01/1983	Desjacques			
	CR 4,370,727	01/1983	Bellet			
	DR 4,377,171	03/1983	Wada			
	ER 4,381,121	04/1983	Hanley			
	FR 4,385,125	05/1983	Preti et al.			
	GR 4,396,020	08/1983	Wolff et al.			
	HR 4,408,905	10/1983	Ehrenkranz			
	IR 4,443,851	04/1984	Lin			
	JR 4,450,239	05/1984	Chatterton			
	KR 4,465,077	08/1984	Schneider			
	LR 4,466,445	08/1984	Abrams			
	MR 4,475,158	10/1984	Elias			
	NR 4,488,560	12/1984	Takamura			

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					Enclosed	No	Enclose	No
	OR WO 90/11521	10/1990	WIPO	BAHAR et al.			X	
	PR WO 91/15594	10/1991	WIPO	CLOUGH et al.			X	
	QR WO 94/02850	02/1994	WIPO	WELLS et al.			X	
	RR WO 94/04926	03/1994	WIPO	CATT et al.			X	
	SR WO 95/16920	06/1995	WIPO	MARCH et al.			X	
	TR 945,670	01/1964	UK				X	
	UR 1 203 619	08/1970	UK				X	
	VR 2 106 646	04/1983	UK	CHATTERTON			X	
	WR 2 045 480	10/1980	UK	OGITA et al.			X	
	XR 2 186 977	08/1987	UK	KUBOUCHI			X	

OTHER (including in this order: Author, Title, Periodical Name, Date, Pertinent Pages, etc.):

	YR	Burger, "The physiologica basis of the fertile period", Fertility and Sterility, Eds. Harrison et al., MTP Press, 1984, pp. 51-58			
	ZR	Burger, "Estradiol: the physiological basis of the fertile period", Int. J. Gynecol Obstet, Suppl 1, 1989, pp 5-9			
	AAR	Campbell, "Methods of monitoring ovarian function and predicting ovulation: summary of a meeting", Research Frontiers in Fertility Regulation, 1985, 3(5), pp 1-16			
	BBR	Cardone et al., "Objective and subjective data for fertile period diagnosis in women: comparison of methods", Clin Exp Obst Gyn, XIX, 1992, 1, pp 15-24			
	CCR	Cekan et al., "The prediction and/or detection of ovulation by means of urinary steroid assays", Contraception, 1986, 33(4), pp 327-345			
	DDR	Collins et al., "The concentrations of urinary oestrone-3-glucuronide, LH and pregnanediol-3a-gluronide as indices of ovarian function", Acta Endocrinologica, 1979, 90, pp 336-347			

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	AR 4,498,481	02/1985	Lemke			
	BR 4,530,366	07/1985	Nessi et al.			
	CR 4,534,362	08/1985	Schumacher et al.			
	DR 4,557,273	12/1985	Stoller et al.			
	ER 4,614,715	09/1986	Tsibris et al.			
	FR 4,670,401	06/1987	Cutler et al.			
	GR 4,685,471	08/1987	Regas et al.			
	HR 4,691,714	09/1987	Wong et al.			
	IR 4,752,880	06/1988	Aeschlimann			
	JR 4,753,247	06/1988	Kirsner			
	KR 4,779,627	10/1988	Kosasky			
	LR 4,770,186	09/1988	Regas et al.			
	MR 4,921,808	05/1990	Schneyer et al.			
	NR 5,043,888	08/1991	Uriarte			

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					Enclosed	No	Enclose	No
	QR 2 116 318	09/1983	UK	BAKER et al.			X	
	PR 1 048 001	02/1979	Canada				X	
	QR 1 183 080	02/1985	Canada	COULSON et al.			X	
	RR 2 290 876	06/1976	France					X
	SR 2 652 092	03/1991	France	REVOL				X
	TR 1 214 438	04/1966	Germany	WILD			X	
	UR 28 03 152	07/1979	Germany				X	
	VR 28 47 397	05/1980	Germany				X	
	WR 3 037 977	05/1982	Germany				X	
	XR 3 221 999	04/1983	Germany				X	

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YR	Collins et al., "Biochemical indices of the fertile period in women", Int J Fertil, 1981, 26(3), pp 196-202			
ZR	Collins et al., "Ovulation prediction and detection by the measurement of steroid glucuronides", Proc X Int Congress on Fertility and Sterility, 1981, pp 19-33			
AAR	Collins et al., "Biochemical methods for predicting ovulation", Fertility and Sterility, 1984, pp 59-69			
BBR	Collins, "Hormonal indices of ovulation and the fertile period", Adv Contracept, 1985, 1, pp 279-294			
CCR	Collins, "Biochemical indices of potential fertility", Int J Gynecol Obstet, 1989, Supl. 1, pp 35-43			
DDR	Collins et al., "Ovarian morphology, endocrine function and intra-follicular blood flow during the peri-ovulatory period", Human Reproduction, 1991, 6(3), pp 319-324			

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	AR	5,050,612	09/1991	Matsumura			
	BR	5,063,903	11/1991	Nucci			
	CR	5,091,170	02/1992	Navot			
	DR	5,137,028	08/1992	Nishimura			
	ER	5/209,238	05/1993	Sundhar			
	FR	5,248,593	09/1993	Hubner-Parajsz et al.			
	GR	4,676,254	06/1987	Frohn			
	HR	5,216,599	06/1993	Uebe et al.			
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	QR	3 247 750	06/1984	Germany				X	
	PR	3 314 442	11/1984	Germany				X	
	QR	3 325 598	01/1985	Germany				X	
	RR	3 342 251	05/1985	Germany				X	
	SR	3 528 964	02/1987	Germany				X	
	TR	3 343 020	06/1985	Germany				X	
	UR	3 609 956	10/1987	Germany				X	
	VR	3 802 479	08/1989	Germany					X
	WR								
	XR								

	YR	Collins (1991) <i>Am J Obstet Gynecol</i> , 165(6), p 1994-1996: 'The evolution of reference methods to monitor ovulation'							
	ZR	Collins (1992) <i>Biochem Soc Trans</i> , 20, p 234-237: 'Immunochemical tests of potential fertility'							
	AAR	Colombo (1989) <i>Int J Gynecol Obstet, Suppl 1</i> , p 13-18: 'Biometrical research on some parameters of the menstrual cycle'							
	BBR	Corsan et al <i>Fertility and Sterility</i> , (1990) 53(4), p 591-601: 'Home urinary luteinizing hormone immunoassays: clinical applications'							
	CCR	Denari et al (1981) <i>Obstetrics & Gynecology</i> , 58 (1), p 5-9: 'Determination of Ovarian Function Using First Morning Urine Steroid Assays'							
	DDR	Djerassi (1990) <i>Science</i> , 1 June 1990, p 1061-1062: 'Fertility Awareness: Jet-Age Rhythm Method?'							

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OTHER (Including in this order: Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

	YR	Fabres et al (1993) <i>Human Reproduction</i> , 8, p 208-210: 'Validation of the dual analyte assay of the oestrone:pregnanediol ratio in monitoring ovarian function'			
	ZR	Flynn (1989) <i>Int J Gynecol Obstet, Suppl 1</i> , p 123-127: 'Natural family planning and the new technologies'			
	AAR	Fordney-Settlage (1981) <i>Int J Fertil</i> , 26, p 161-169: 'A Review of Cervical Mucus and Sperm Interactions in Humans'			
	BBR	France et al (1975) <i>J Reprod Fert, Suppl 22</i> , p 107-120: 'The Detection of Ovulation in Humans and its Applications in Contraception'			
	CCR	Garcia et al (1981) <i>Fertility and Sterility</i> , 36(3), p 308-315: 'Prediction of the Time of Ovulation'			
	DDR	Gudgeon et al (1989) <i>The Medical Journal of Australia</i> , 152, p 344, 346 and 349: 'Evaluation of the accuracy of the home ovulation detection kit, Clearplan, at predicting ovulation'			

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	YR	Hatcher et al (1994) <i>Contraceptive Technology</i> , 16th Revised Edn, Irvington Publishers, NY, p 327-340: 'Fertility Awareness'			
	ZR	Ismail et al (1989) <i>Contraception</i> , 39(1), p 53-71: 'An evaluation of the Bioself 110 fertility indicator'			
	AAR	Judge et al (1978) <i>Steroids</i> , 31(2), p 175-187: 'Time-Course Relationships between Serum LH, Serum Progesterone and Urinary Pregnanediol Concentrations in Normal Women'			
	BBR	Katz et al (1991) <i>Journal of Andrology</i> , January/February 1991, Abstract 29: 'Human Cervical Mucus Properties and Sperm Mucus Interaction during the Proliferative Phase of the Menstrual Cycle'			
	CCR	Katz (1991) <i>Am J Obstet Gynecol</i> , 165(6), Part 2, p 1984-1986: 'Human cervical mucus: Research update'			
	DDR	Kerin et al (1981) <i>British J Obstet Gynecol</i> , 88(2), p 81-90: 'Morphological and Functional Relations of Graafian Follicle Growth to Ovulation in Women Using Ultrasonic, Laparoscopic and Biochemical Measurements'			

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	YR	Lauzon et al (1992) <i>J Steroid Biochem Molec Biol</i> , 42(2), p 223-228: 'A Direct Dot-Enzyme Immunoassay to Detect Human Ovulation'			
	ZR	Lewis et al (1993) <i>New Zealand Medical Journal</i> , 28 April 1993, p 165-166: 'Recycling ovulation markers'			
	AAR	Lewis et al (1994) <i>Steroids</i> , 59, p 288-291: 'Re-examining steroid hormone metabolites as ovulation markers using monoclonal antibodies'			
	BBR	Landgren et al (1980) <i>Acta Endocrinologica</i> , 94, p 89-98: 'Hormonal profile of the cycle in 68 normally menstruating women'			
	CCR	May (1989) <i>Proceedings of "Biotech '89" Conference</i> , Blenheim Online Publications, p 291-295: 'Clearblue One Step: adapting technology to the needs of the consumer'			
	DDR	Moghissi et al (1972) <i>Am J Obstet Gynecol</i> , 114(3), p 405-418: 'A composite picture of the menstrual cycle'			

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BY APPLICANT

Applicant: CATT et al.

Appln. No.: 08/801,212

Filing Date: FEBRUARY 18, 1997

Date: August 2, 2000

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Examiner: J. SNAY

Group Art Unit: 1743

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YR	Moghissi (1980) <i>Fertility and Sterility</i> , 34(2), p 89-98: 'Prediction and Detection of Ovulation'			
ZR	Moghissi (1992) <i>Reproductive Endocrinology</i> , 21(1) p 39-55: 'Ovulation Detection'			
AAR	Munro et al (1991) <i>Clin Chem</i> , 37 (6), p 838-844: 'Relationship of Serum Estradiol and Progesterone Concentrations to the Excretion Profiles of Their Major Urinary Metabolites as Measured by Enzyme Immunoassay and Radioimmunoassay'			
BBR	Paz et al (1990) <i>Gynecol Obstet Invest</i> , 29, p 207-210: 'Determination of Urinary Luteinizing Hormone for Prediction of Ovulation'			
CCR	<i>Population Reports</i> , Series 1, No 3, September 1991, p 1-33 - 1-71: 'Periodic Abstinence: How well do new approaches work?'			
DDR	Royston (1982) <i>Biometrics</i> , 38, p 397-406: 'Basal Body Temperature, Ovulation and the Risk of Conception, with Special Reference to the Lifetimes of Sperm and Egg'			

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To:

Atty.

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AAR	Singh et al (1984) <i>Fertility and Sterility</i> , 41(2), p 210-217: 'Clinical validation of enzymeimmunoassay of human luteinizing hormone (hLH) in the detection of the preovulatory luteinizing (LH) surge in urine'			
BBR	Singh et al (1984) <i>Hormone Receptors in Growth and Reproduction</i> , ed Saxena et al, Raven Press, NY, p 341-350: 'Clinical Validation of Enzyme Immunoassay for the Detection of the Preovulatory Luteinizing Hormone Surge in Urine'			
CCR	Stanczyk et al (1980) <i>Am J Obstet Gynecol</i> , 137(4), p 443-450: 'Direct radioimmunoassay of urinary estrogen and pregnanediol glucuronides during the menstrual cycle'			
DDR	<i>The Economist</i> , March 23, 1991, p 128-129: 'Fertility: Keeping the beat'			

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AAR	Weerasekera et al (1983) <i>J Steroid Biochem</i> , 18(4), p 465-470: 'Multiple Immunoassay: The Simultaneous Measurement of Two Urinary Steroid Glucuronides as an Index of Ovarian Function'			
BBR	WHO Task Force (1980) <i>Am J Obstet Gynecol</i> , 138(4), p 383-390: 'Temporal relationships between ovulation and defined changes in the concentration of plasma estradiol-17beta, luteinizing hormone, follicle-stimulating hormone, and progesterone'			
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	YR	WHO Task Force (1983) <i>Fertility and Sterility</i> , 40 (6), p 773-778: 'A prospective multicentre trial of the ovulation method of natural family planning. III. Characteristics of the menstrual cycle and of the fertile phase'			
	ZR	WHO Task Force (1985) <i>Int J Fertil</i> , 30(3), p 18-30: 'A Prospective Multicentre Study to Develop Universal Immunochemical Tests for Predicting the Fertile Period in Women'			
	AAR	Wright et al (1979) <i>Steroids</i> , 34(4), p 445-457: 'Urinary excretion of estrone glucosiduronate, 17beta-estradiol-17-glucosiduronate, and estriol-16alphaglucosiduronate. Significance of proportionate differences during the menstrual cycle. I. Probit analysis'			
	BBR	Yong et al (1989) <i>Aust NZ J Obstet Gynecol</i> , 29, p 155-160: 'Simple Office Methods to Predict Ovulation: The Clinical Usefulness of a New Urine Luteinizing Hormone Kit Compared to Basal Body Temperature, Cervical Mucus and Ultrasound'			
	CCR	Zinaman et al (1989) <i>Biology of Reproduction</i> , 41, p 790-797: 'The Physiology of Sperm Recovered from the Human Cervix: Acrosomal Status and Response to Inducers of the Acrosome Reaction'			
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